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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/564,484	03/16/2006	Yoshinori Kosugi	2006_0026A	7353

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EXAMINER	
VENCI, DAVID J	
ART UNIT	PAPER NUMBER
1641	
MAIL DATE	DELIVERY MODE
06/24/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/564,484	KOSUGI ET AL.	
	Examiner	Art Unit	
	DAVID J. VENCI	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *January 15, 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-14* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-14* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Unity of Invention

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1. Restriction is required under 35 U.S.C. 121 and 372.

I. Claims 1 and 7, drawn to diagnostic methods incorporating two antibodies.

II. Claims 1 and 8, drawn to diagnostic methods incorporating immunohistochemistry.

III. Claims 2, 4-6 and 12, drawn to an antibody recognizing HRF.

IV. Claims 3-6, drawn to an antibody binding an epitope.

V. Claim 9, drawn to a kit subcombination comprising labeled antibodies against HRF.

VI. Claim 10, drawn to a kit combination comprising a labeled antibody against an epitope.

VII. Claim 11, drawn to a kit combination comprising a support.

VIII. Claim 13, drawn to a therapeutic composition.

IX. Claim 14, drawn to a therapeutic method.

According to PCT Rules 13.1 and 13.2, inventions must form a single general inventive concept by sharing a common technical feature that contributes over the prior art. However, Inventions I through IX do not form such a single general inventive concept because the technical feature common to Inventions I through IX does not contribute over the prior art.

Specifically, the antibodies of Invention III and IV are components of the kits and composition of Inventions V, VI, VII and VIII, and are used in the methods of Inventions I, II and IX. However, Sanchez *et al.*, 18 ELECTROPHORESIS 150 (1997), describes the antibodies of Invention III and IV (see Section 2.3 Antibody production and immunoblot analysis).

Therefore, unity of invention is lacking because Inventions I through IX do not form a single general inventive concept by sharing a common technical feature that contributes over the prior art. In accordance with 37 CFR 1.499, Applicants are required, in reply to this action, to elect a single invention to which the claims must be restricted.

This application contains claims directed to the following patentably distinct species:

1. Select ONE antibody "source" from:
    a. mammal vaccinated with "a peptide containing a sequence of 5 to 20 amino acid residues selected from the amino acid sequence at positions 90 to 130 of SEQ ID NO:2" immunogen (claim 4);
    b. mammal vaccinated with "a peptide containing a sequence of 5 to 20 amino acid residues selected from the amino acid sequence at positions 1 to 95 of SEQ ID NO:2" immunogen (claim 5);
    c. mammal vaccinated with "a peptide containing a sequence of 5 to 20 amino acid residues selected from the amino acid sequence at positions 115 to 172 of SEQ ID NO:2" immunogen (claim 6).

Applicants are required to elect ONE antibody "source" from 1(a), 1(b) or 1(c). Examination on the merits shall be restricted to Applicants' elected species so long as generic claims 1, 2 7-11, 13 or 14 are under rejection. Upon allowance of a generic claim, Applicants are entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of the allowable generic claim as provided by 37 CFR 1.141.

The antibody species lack unity of invention because they do not form a single general inventive concept under PCT Rule 13.1 and lack the same special technical feature under PCT Rule 13.2 by virtue of having been sourced from mammals vaccinated with different immunogens.

Applicant is advised that a complete reply to this requirement must include: (i) elections of both a species and invention to be examined, even if the requirement is traversed[1] (37 CFR 1.143), and (ii) identification of the claims encompassing the elected invention and species. An argument that claims are allowable or that all claims are generic is considered non-responsive unless accompanied by a complete election.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication should be directed to David Venci whose telephone number is (571)272-2879. The examiner can normally be reached on 08:00 - 16:30 (EST). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

[1] Applicant may elect an invention or species with traverse or without traverse. To reserve a right to petition, Applicant must elect *with traverse*. Should Applicant traverse on the ground that the inventions or species are not patentably distinct from each other, Applicant should clearly admit on the record, or submit or identify evidence already on the record that the inventions or species are obvious variants over each other. However, if Examiner finds one Invention or species unpatentable over prior art, Examiner may use the evidence or admission of record to reject other inventions or species under 35 U.S.C.103(a). If Applicant elects *with traverse* but does not distinctly and specifically point out supposed errors in this restriction requirement, then Applicant's election is considered incomplete and treated as an election *without traverse* pursuant to MPEP § 818.03(a). Failure to timely argue in support of traversal will result in the loss of right to petition under 37 CFR 1.144.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

David J Venci
Assistant Examiner
Art Unit 1641

/Long V Le/
Supervisory Patent Examiner, Art Unit 1641